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Pulse radiofrequency neuromodulation analgesic therapy has no effect on the function of permanent pacemaker: a case report of 3 successful cases

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Abstract

Chronic low back pain (CLBP) is a common problem all over the world and there are more and more patients with electronic device implantation. In recent decades, pulse radiofrequency (PRF) neuromodulation is considered a potentially effective therapy for CLBP, but there is still concern about safety when using it on patients with electronic device implantation. Here we provide with three successful cases of using PRF neuromodulation on patients with permanent pacemaker (PPM) implantation.

Patient 1 is an 88-year-old male who has PPM (mode unknown) for arrhythmia for many years. He underwent PRF (45V, 240 times, 42°C) for bilateral L4 and L5 radiculopathy three times; each time was done safely without sequela. **Patient 2** is an 84-year-old female who has PPM (mode DDD) implanted in 2011/09 for sick sinus syndrome. She underwent PRF (60V or 45V, 240 times, 42°C) three times for fail back surgery syndrome and sciatica of bilateral L2; each time was done safely without sequela. **Patient 3** is a 77-year-old female who has PPM (mode unknown) implanted in 2014/12 for sick sinus syndrome. She underwent PRF (50V, 120 sec, 42°C) once without sequela.

PRF had been considered to be contra-indicated for patients with PPM but without strong evidence. According to the physical features and neuromodulation mechanism of PRF, a current passes from an electrode to tissue and finally leaves from ground plate. It generates heat on the tip of the electrode, which causes thermal damage to target tissue and modulates the signals of neurotransmitters or inflammatory factors.

In our opinion, the reason why it is safe to use PRF on patients with PPM may due to the fact that the electrode is so far from the heart and PPM that the electric circuit does not pass through the heart and PPM. It is also possible that the energy

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required for PRF is not high enough to influence the PPM. Our three successful cases present that PRF neuromodulation can be used safely on CLBP patients with PPM. We also discuss the possible impacts of PRF on other implantable electronic devices. Further data are needed to prove the safety of PRF for patients with permanent electronic device implantation.

Introduction

The prevalence of low back pain (LBP) has been reported among many people especially from work related and occupational activities. Among the 75-84% of the general population that suffer LBP, it is estimated that 5-10% of the people result in severe morbidity, increased health care costs, sick leaves and individual suffering.(1) Current treatments for CLBP include medication (mostly NSAIDs or weak opioid), exercise therapy, multidisciplinary rehabilitation, psychosocial strategies, spinal manipulation, acupuncture, or invasive treatments like surgery, caudal injection, or PRF neruomodulation.(2) When PRF neruomodulation becomes more and more popular for those who have poor response to conservative treatment, the safety of PRF has been placed under increased scrutiny. In patients with implanted electronic devices (e.g. permanent pacemaker (PPM)), PRF is thought to possibly interfere the electric signals, which may lead to device malfunction or even harm to patients. However, in recent years, there are case reports which indicate that undergo PRF on those who have PPM or ICD implantation is safe and without interference to the devices.(3) There are also researchers trying to conclude a guideline to safely use PRF on those patients. After reading these case reports, we found that there is still no clear conclusion if PRF can be used safely on patients with PPM implantation. Therefore we are going to provide three successful cases in our hospital with detailed information, and we hope this can be a strong evidence to convince that PRF neuromodulation can be used safely on CLBP patients with PPM implantation.

Case Report

Patient 1 is an 88-year-old male with coronary artery disease s/p 1 stent placement and arrhythmia s/p pacemaker implantation. He suffered from severe aching and shooting pain on low back with radiation to bilateral legs for more than 3 months. The worst VAS score was 10. The pain exacerbated when standing. Pain pills and intramuscular analgesics injection provided limited effect. Therefore he came to our OPD for help. Thoracolumbar spine x-ray showed Grade I-II spondylolisthesis of T12 on L1, degenerative disc disease of T11-12, T12-L1, L1-2, L2-3, L3-4, compression fracture of L1~L5 s/p vertebroplasty, and spondylosis of thoracolumbar spine. Ultrasound-guided caudal injection with 0.1% Levobupivacaine and steroid was performed, and the VAS score had improved but relapsed gradually. He then decided to proceed for PRF neuromodulation to prolong analgesia. PRF on roots of bilateral L4 and left L5 was done in 2017/05, and then bilateral L4 and L5 in 2018/08 and 2019/03. All three times are without any sequela.

Patient 2 is an 84-year-old female with sick sinus syndrome s/p permanent pace maker implantation

(mode DDD) in 2011/09. She had suffered from low back pain for more than 10 years, the worst VAS score was 6~7. The pain aggravated when standing or sitting for long time, turning, and leg raising, mild relieved by lying down. She had visited our OPD of neurosurgeon department and received L2-5 laminectomy for L2-L5 stenosis and L1+L2+L4 vertebroplasty for compression fracture. However her symptoms didn't improve much. Fail back surgery syndrome was diagnosed. She kept visiting rehabilitation department and pain management department for her severe back pain but in vain. She received caudal injection several times; VAS shortly improved after injection but soon recurred in about a week. She finally received PRF over bilateral L1 and L2 root in 2018/01, 2018/08 and 2019/06. No sequela happened during each treatment.

Patient 3 is a 77-year-old female with sick sinus syndrome s/p permanent pacemaker implantation. She suffered from severe back pain for more than six months. She visited OPD of pain management department since 2016/02. Image survey showed suspect degenerative disc disease in T and L spine and bilateral knees. She received X-ray guided transforaminal epidural injection to right L1 root; VAS score improved a lot after injection but relapsed about three months later. She then agreed to receive PRF neuromodulation in 2017/03. The procedure was done safely without sequela.

PRF intervention protocol: When undergoing PRF, we kept the patient awake so the patient could give feedback immediately if there were any complications. Initially, we used 5-lead EKG monitor and arterial line to monitor the patient's condition, with also an external cardiac pacemaker standby. All the three cases were successfully done with PRF, without any discomfort or arrhythmia detected. The PRF of all three cases were presented in following Table 1.

Patient No.	Diagnosis				Procedure	
Date	Site	Temperature	V	Times	Im(Ω^{-1})	mA
Patient 1	Lumbosacral radiculopathy, bilateral L4 and L5				PRF	
2017/05	Left L4	42°C	45	120sec	506	117
2018/08	Right L4	42°C	45	240 times	343	202
	Right L5	42°C	45	240 times	420	184
	Left L4	42°C	45	240 times	233	285
	Left L5	42°C	45	240 times	484	195
2019/03	Right L4	42°C	45	240 times	380	160
	Right L5	42°C	45	240 times	420	153
	Left L4	42°C	45	240 times	420	158
	Left L5	42°C	45	240 times	590	121
Patient 2	Fail back surgery syndrome, sciatica				PRF	
2018/01	Right L1-L2	42°C	60	240 times	316	257
	Left L1-L2	42°C	60	240 times	341	254
2018/08	Right L2-L3	42°C	45	240 times	430	145
	Left L2-L3	42°C	45	240 times	470	130
2019/06	Right L2	42°C	45	240 times	400	148
	Left L2	42°C	45	240 times	388	149
Patient 3	Right L1 radiculopathy				PRF	
2017/03	Right L1	42°C	50	120sec	1045	95

▲ Table 1: PRF information of the 3 patients

Discussion

Mechanism of PRF

First, an electrode is inserted to target site by fluoroscopy. An electric circuit is established by applying ground plate on the patient, then the current will go from the electrode, through the tissue, and finally leave the patient from the ground plate. The area with highest temperature is supposed to be at the tip of the electrode. After all is set, two bursts of 20 msec of active phase followed by 280 msec of silent phase each of an alternating current are delivered in 1 second. The oscillating frequency of the alternating current is usually set at 500,000 Hz, and the output at 45V. If the electrode tip temperature exceeds 42°C, the voltage will be decreased or it will result in nonselective destruction of both myelinated and nonmyelinated nerve fibers,

which is not our desired result.(4) Beside heat, the tissue near the target will also be exposed to RF electric field. Fortunately, it has no effects on cell morphology, devision rate and respiration. The set frequency is 500,000 Hz, which is far higher than the physiological threshold that cannot induce cell depolarization.(5)

Initially it was thought that PRF causes denervation by selectively heating of nervous structure, causing thermal damage, leading to blockage to neural signal transmission. This should also lead to other sensory loss, however pain relief effect lasts longer than other sensory loss. There must be other biological effects in addition to simply thermal damage. First of all, it's found that PRF alters synaptic transmission. An in vitro study finds PRF to induce transient decrease in excitatory postsynaptic potential. Increased expression of c-Fos in the dorsal horn and activated transcription factor 3 (ATF3) in small-diameter C and Aδ fibers is observed.(4; 6) Moreover, PRF also influences inflammatory factors like TNFα, or neurotrophins, therefore improves pain sensation.(7)

Complications of PRF

Common complications of PRF include bleeding, infection, neuritis, and unintentional damage to surrounding tissue. Specific complications are also dictated by the neuroanatomical site, include weakness and paralysis with ablation of structures close to the vertebral column, as well as meningitis, intracerebral hemorrhage, CSF leak, and deafferentation pain in gasserian and sphenopalatine ganglion PRF.(8) In patients with PPM, concerns on receiving PRF neuromodulation are similar to those when undergoing other electromagnetic procedures. These include asynchronous pacing, oversensing, mode switch or pacing inhibition, or transient reset.(9) A PPM can be roughly divided to three parts: sensor leads, battery, and pulse generator. The most common electromagnetic interference (EMI) usually happens at the sensor leads of PPM, including undersensing, oversensing, or noncapture. Undersensing means failure to sense native intracardiac depolarization, possibly due to lead disorder, electrolyte disorder, or myocardial process disorder. Oversensing usually caused by intracardiac electrical signals other than the intrinsic depolarization of a cardiac chamber. This is more likely to happen when ventricular lead senses a high-amplitude T wave, myopotentials, or hospital/environmental EMI. Noncapture is that PPM fail to capture the depolarization of the myocardial tissue.(10) Though it is rare to have EMI on battery or pulse generator, EMI may also cause a power-on reset, generator damage, atrial and ventricular arrhythmia, or tissue injury at the lead-tissue interface.(11)(12)

Reviewing the case reports of RF done on patients with PPM implantation, we found a 1995 study which looked at PPM activity in 25 patients with 13 different devices undergoing RF Neurotomy for tachyarrythmia had reported sensing failure (32.0%) and pacing failure (16.0%) in patient. However no pacemaker damage was seen.(13) Reports about complication of PRF using on pain management was not found, either.

To minimize the risk of affecting PPM, it is suggested to avoid current pathway passing by the PPM and the pacing leads; ideal operation distance should be over 15 cm from pacing leads. In addition, using short-duration cautery burst less than 5 second also lower the risk of complication.(14) PRF bursts only last for 20 msec(4), which is far shorter than the recommended value, is therefore considered safe. Moreover, there is consensus that using bipolar device in electromagnetic procedures is safer than using monopolar device.(12)

PRF on patient with other implanted electric devices

Implantable Cardioverter Defibrillators (ICD): ICDs are similar to PPM, using a sensor lead to detect life-

threatening ventricular arrhythmias, then give rapid overdrive pacing or an internal defibrillator shock. The possible EMI and complications are similar to what PPM may encounter, and the processes to avoid them are also more or less the same as that in PPM. (12)

Cochlear Implants: EMI has the potential to cause irreparable damage to cochlear devices by producing voltage of such magnitude that a direct coupling can exist between the electrosurgical tip and a cochlear implant electrode. According to the manufacturer, monopolar device is strictly inhibited, but bipolar device is acceptable when it is kept at least 3 cm from the implant package and electrodes, and when it is sure to avoid current pathway through the head and neck region of the patient.(12) In the cases of PRF neuromodulation using on treating CLBP, the electrode and the ground plate are both placed at lower part of the body, which is surely avoiding current pathway through the head and neck region, and may therefore be safe.

Deep brain stimulator (DBS): There is no immediate safety concern in patients with DBS, but temporary device malfunction has been reported in two cases. The patient experienced immediate lancinating ‘‘electric shock’’ sensations, but recovered as soon as the procedure stopped, and there was no any change in device parameters during postoperative checkup. After changing procedure protocol to make the current pathway away from the device, the patient didn’t experience the electric shock sensation again.(12) Since the device sensor is mostly placed at head and neck region, it may be safe when receiving PRF in CLBP because of enough distance from current pathway to the device.

There are still many other electronic implantable devices, however it is hard to make sure the distance between electric circuit and the device system is far enough. As a result, there may be safety concerns for these patients and it is suggested that these devices should be turned off when receiving electromagnetic procedures.

Our experience

In our opinion, in PRF for CLBP, the targeted sites are usually at lumbar level, which is not very close to heart and PPM, and the current pathway doesn’t pass near heart and PPM. Moreover, the energy needed for PRF is not very high. Many PPMs are designed to tolerance a high degree of electrical and magnetic fields, so in most situations the procedure can be done safely. Even if there is interference, the effects on PPM are usually temporary, only strong energy field (e.g gamma radiation or very strong magnetic fields) will cause permanent effects.(15) Theoretically PRF shouldn’t cause EMI on PPMs. That’s why we decided to give it a try to let more patients benefit from PRF neuromodulation, and our results supported our hypothesis that PRF can be used safely on patients with PPM implantation as well.

Conclusion

Our results and resources suggested that the PRF neuromodulation can be safely applied to patients carrying PPM. As we considered PRF available, we would like to extend our cohort to patients using other electronic devices, such as ICD, deep brain stimulator. Our long experience in PRF allows us to safely administer the easy and long-lasting procedure to this kind of patients.

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高頻熱燒灼神經調控止痛術對永久植入的心臟節律器功能無影響：3 個成功病例報告

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慢性下背痛是一個常見的問題，同時裝設電子植入設備的病患也越來越多。近年來，高頻熱燒灼神經調控止痛術被認為是一個相當有潛力的治療方法，但因為不確定它會不會對那些裝置的功能有影響，大家對其安全性一直有顧慮。在這篇文章我們提供了三個成功將高頻熱燒灼神經調控止痛術使用在裝有心臟節律器病患身上的案例。病患 1 是一位 88 歲男性，因為心律不整已裝設心臟節律器多年。他因為雙側 L4 及 L5 神經痛而接受總共三次高頻熱燒灼術 (45V,42° C)，每次都沒有發生節律器干擾或其他併發症。病患 2 是一位 84 歲女性，她因病竇症候群在 2011 年 9 月裝了心臟節律器。由於背部術後疼痛症候群及雙側 L2 坐骨神經痛，她接受了總共三次的高頻熱燒灼術 (60V/45V,42° C)，每次都沒有發生節律器干擾或其他併發症。病患 3 是一位 77 歲女性，她因病竇症候群在 2014 年 12 月裝了心臟節律器。她接受了一次高頻熱燒灼術 (50V,42° C)，沒有發生節律器干擾或其他併發症。高頻熱燒灼術被認為會干擾心臟節律器，但是一直沒有明確的證據。我們研究了高頻熱燒灼術的物理特性還有機制，發現它是藉由一個電流產生熱，造成組織的熱傷害來達到止痛效果，並且也會藉由干擾神經傳導物質或是發炎物質的分泌來影響痛覺傳導，而這個電流會從電極經由組織，最後從接地貼片離開人體。所以我們認為因為電流並沒有通過心臟或是心臟節律器的感應器並離他們有足夠的距離，再加上高頻熱燒術所需的能量並不高，所以使用在裝有心臟節律器的病患身上應該是沒有問題的。我們的三個成功案例也支持我們的想法。我們也討論關於高頻熱燒灼術使用在裝設其他電子植入設備的病患的可行性，但這個部分還需要更多的數據跟證據支持。

關鍵字：高頻熱燒灼神經調控，止痛，心臟節律器，下背痛

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